UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS MYLAN INC. AND MYLAN PHARMACEUTICALS INC.'S REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY JUDGMENT

PRELIMINARY STATEMENT

In California's Memorandum in Opposition to Defendant Mylan's Motion for Partial Summary Judgment (the "Opposition Brief"), California contends that any claims it has against Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, "Mylan") that accrued before July 1999 are not time barred because Mylan has not shown that California did not discover the claims sooner. This argument misapplies the law. In fact, it is California's burden to demonstrate that it could not have discovered the claims earlier if it wishes to recover for claims that accrued prior to the three year statute of limitations governing claims under the California False Claims Act (the "CFCA"). Since California has failed to adduce any evidence that it could not have discovered any claims it may have had against Mylan before July 1999, those claims are barred as a matter of law. California's argument that the evidence cited by Mylan was not sufficient to demonstrate "discovery" by California is irrelevant, as California has the burden of showing that the discovery rule applies. In any event, California's argument is meritless, as the

evidence cited by Mylan was sufficient to put California on notice that "AWP had become unhinged from acquisition costs." *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d 20, 78 (D. Mass. 2007).

California attempts to counter Mylan's argument that the margins that resulted from California's reimbursement methodology for the Mylan drugs at issue in this action were relatively modest in actual dollar terms by claiming that Mylan "cherry-picked" the drugs it cited as examples. This argument is demonstrably false. The Subject Drugs that Mylan cited as examples are among the Mylan Subject Drugs with the highest dollar amount of reimbursements paid by California. The drugs that California cites are not. Moreover, the modest margins for these drugs reflect the modest margins for the Mylan Subject Drugs overall.

I. CALIFORNIA'S CLAIMS PRIOR TO JULY 1999 ARE BARRED BY THE STATUTE OF LIMITATIONS

A. California Bears the Burden of Establishing That the Discovery Rule Applies

The CFCA's statute of limitations bars any claim "filed more than three years after the date of discovery by the official of the state or political subdivision charged with responsibility to act in the circumstances". *See* CAL. GOV'T CODE § 12654(a). Under the CFCA, "discovery" occurs when the responsible public official "either knows of the false claim or knows of facts which would lead a reasonably prudent person to *suspect* it." *Debro v. Los Angeles Raiders*, 92 Cal. App. 4th 940, 953 (Cal. Ct. App. 2001). The *Debro* court held that the term "discovery" in Section 12654(a) of the California Government Code should be construed the same way as it had been by California courts applying "the discovery rule" under analogous fraud statutes. *Id*. at 950-51.

California's argument that Mylan has failed to meet its burden of showing that California discovered claims it may have had against Mylan sooner misapplies the law. In fact,

the law is the opposite; when applying the discovery rule, "the court places the burden on the plaintiff to 'show diligence'." *Fox v. Ethicon Endo-Surgery, Inc.*, 110 P.3d 914, 921 (Cal. 2005); *see also Clemens v. DaimlerChrysler Corp.*, 534 F.3d 1017, 1024 (9th Cir. 2008) (quoting *Bedolla v. Logan & Frazer*, 52 Cal. App. 3d 118, 129 (Cal. 1975) ("A plaintiff must affirmatively excuse his failure to discover the fraud within three years by showing that he was not negligent in failing to make the discovery sooner and that he had no actual or presumptive knowledge of facts sufficient to put him on inquiry.") California must show "(1) when the fraud was discovered; (2) the circumstances under which it was discovered; and (3) that [California] was not at fault for failing to discover it or had no actual or presumptive knowledge of facts sufficient to put [it] on inquiry." *Clemens*, 534 F.3d at 1024 (quoting *Baker v. Beech Aircraft Corp.*, 39 Cal. App. 3d 315, 321 (Cal. 1974)).

California has completely failed to meet its burden here. In its opposition papers, California has failed to adduce one scintilla of evidence that would tend to establish any of the elements of the discovery rule. California's attempts to criticize the evidence Mylan has adduced to show that it did have inquiry notice of its claims are beside the point. Mylan did not have the burden to show any evidence on this question. Since California has not even attempted to meet its burden to show that the discovery rule in California Government Code § 12654(a) should apply to its claims against Mylan, the Court should grant Mylan's motion on these grounds alone.

B. The Evidence In The Record Was Sufficient To Put California On Reasonable Notice of Its Claims Against Mylan

The discovery rule contained in California Government Code § 12654(a) starts the three year statute of limitations running from the date of the discovery of either the false claim itself "or facts that would lead a reasonably prudent person to suspect [a false claim.]"

Debro, 92 Cal. App. 4th at 950. Despite California's contentions about giving the provisions of the CFCA a "broad" reading, California is beholden to the same discovery rule as all other plaintiffs once it has been put on inquiry notice of a fraud. As the court in *Debro* held, "*any* plaintiff has a duty to inquire once he becomes aware of facts that would make a reasonably prudent person suspect fraud." *Id*. at 951 (emphasis in the original). In the drug pricing context, "[u]nder the discovery rule, the question is when there was sufficient information such that a reasonable [third party payor] in the plaintiffs' position would have been on notice to investigate the possibility that AWP had become unhinged from acquisition costs causing plaintiffs to overpay for drugs." *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d at 78. The HHS-OIG report "Review of Pharmacy Acquisition Costs for Drugs Reimbursed Under the Medicaid Prescription Drug Program of the California Department of Health Services" (A-06-95-00062) (Robben Decl. Ex. 20) (the "California Report") and the original *qui tam* complaint in this action (Robben Decl. Ex. 40) were more than sufficient to meet this standard.[1]

The California Report, which was published in March 1996 and documented a HHS-OIG survey of California pharmacies in 1994 and 1995, explained that AWPs were set by manufacturers (such as Mylan), who reported them to pricing compendia. California Report at 1. The OIG report documented for California that pharmacists could purchase generic drugs for an average of 41.4 percent below published AWPs (or, in California's parlance, a "spread" of 70.6 percent). California Report at Appx. 3. When the results from the survey were broken down by the category of the pharmacy surveyed, the California Report documented that rural independent pharmacies, rural chain pharmacies, urban independent pharmacies, and non-traditional

[1] "Robben Decl." refers to the Declaration of Philip D. Robben In Support of Defendants' Motions for Partial Summary Judgment, dated Nov. 25, 2009 (Dkt. No. 6702), the Corrected Declaration of Philip D. Robben In Opposition to Plaintiff's Motion for Partial Summary Judgment, dated Dec. 21, 2009 (Dkt. No. 6799), and the Declaration of Philip D. Robben in Further Support of Defendants' Motions for Partial Summary Judgment, dated Jan. 15, 2010, and the exhibits annexed thereto.

pharmacies could all purchase generic drugs at more than 50 percent below AWP (or at a spread of more than 100 percent). *Id.*

The original *qui tam* complaint in this action, filed by Ven-A-Care in July 1998, similarly documented large differences between published AWPs and actual acquisition costs for California by specifically laying out published AWPs alongside Ven-A-Care's alleged "catalog price" 23 manufacturers' drugs, some of which exceeded 500 percent. *See* Robben Decl., Ex. 40 at 105-107. That complaint also sets forth the same alleged scheme that California described in its August 2005 complaint in intervention, namely that manufacturers caused to be published AWPs that exceeded Medi-Cal providers' actual costs, which in turn resulted in Medi-Cal reimbursement payments that also exceeded providers' costs. *Id*. at 4-6.

California does not dispute any of this evidence, but instead contends (without legal support) that it was not sufficient to put California on notice of its claims against Mylan. California's arguments are meritless. California contends that the California Report was not sufficient because it did not contain allegations of fraudulent conduct. Such a showing is not required:

> A plaintiff need not be aware of the specific "facts" necessary to establish the claim; that is a process contemplated by pretrial discovery. Once the plaintiff has a suspicion of wrongdoing, and therefore an incentive to sue, she must decide whether to file suit or sit on her rights. So long as suspicion exists, it is clear that the plaintiff must go find the facts; she cannot wait for the facts to find her.

Jolly v. Eli Lilly & Co., 751 P.2d 923, 928 (Cal. 1988). The California Report set forth (a) that AWPs were controlled by drug manufacturers, like Mylan, (b) that AWPs for generic drugs were, on average, almost double providers' actual costs, and (c) that as a result, Medicaid pharmacy reimbursement payments substantially exceeded providers' actual costs. This is precisely the allegation that California has leveled against Mylan and the other defendants in this

action. That the California Report did not label it as fraud at that time does not help California – indeed, it is further evidence that California's current characterization of Mylan's actions as "fraudulent" is without merit. In any event, the Report was more than sufficient to put California on notice of any potential claims.

California also argues that the California Report and the original *qui tam* complaint were not sufficient to put it on notice of its claims against Mylan because they did not specifically name Mylan or any of Mylan's drugs. There is no legal support for this argument either. Under California law, a plaintiff need not know the identity of the defendant to be on inquiry notice of her claim, provided that she knows someone has caused her injury. *Jolly*, 751 P.2d at 930 (Cal. 1988) ("Plaintiff does not dispute the general rule that ignorance of the identity of the defendant does not affect the statute of limitations.") In this case, the California Report and the original *qui tam* complaint put California on notice of an industry-wide phenomenon of manufacturers reporting AWPs that far exceeded actual costs for generic drugs. This information was more than enough to put California on inquiry notice that the AWPs reported by a large generic manufacturer like Mylan would likely significantly exceed providers' acquisition cost.

California attempts to distinguish this case from *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 491 F. Supp. 2d at 31-32, wherein the MDL Court held that – as a result of reports issued by the OIG that were similar to the California Report and Congress's passage of the Balanced Budget Act of 1997 – private third party payors such as Blue Cross Blue Shield were on inquiry notice of their claims by no later than 1997, by arguing that the MDL Court reached that decision after a bench trial, not on summary judgment. On the same grounds, California attempts to analogize this case to *Massachusetts v. Mylan Labs.*, 608 F.

Supp. 2d 127, 160 (D. Mass. 2007), wherein the MDL Court declined to grant summary judgment on statute of limitations grounds because it found issues of fact in the record. These arguments fail. "[W]here uncontradicted facts established through discovery are susceptible to only one legitimate inference, summary judgment [on statute of limitations issues] is proper." *Jolly*, 751 P.2d at 928-29. In this case, Mylan has put forth evidence to show that California was on inquiry notice of any claims it may have against Mylan by no later than July 1998. California, which has the burden of establishing that the discovery rule applies at all, has failed to adduce any evidence to the contrary. Therefore, there are no issues of fact that require resolution by a fact finder, and summary judgment on the statute of limitations is appropriate.

II. CALIFORNIA DID NOT OVERPAY FOR THE MYLAN DRUGS

In response to Mylan's demonstration that Medi-Cal reimbursement payments for the Mylan Subject Drugs result in relatively modest margins for pharmacies, California contends that Mylan has "cherry-picked" drugs that it used as examples.[2] This argument is demonstrably false. In fact, the drugs used as examples were chosen from a list of the fifteen Mylan Subject Drugs with the highest dollar amount of ingredient reimbursement per drug at issue in this action, as compiled by Mylan's expert, Prof. David Bradford. *See* Palermo Decl. Ex. W, at p. 8 Figure 2.[3] For instance, the claims data produced by California show that there were

[2] Plaintiff's assertion that the Declaration of Peter Brase (Dkt. No. 6706) ("Brase Decl.") submitted in support of this point lacks foundation and contains improper expert testimony by a lay witness is meritless. As set forth in his declaration, Mr. Brase merely performed simple arithmetic to determine the margin between reimbursement payments contained in claims data produced by California and the providers cost to acquire and dispense those drugs, as reported in the Myers and Stauffer report produced by California. *See* Brase Decl. at ¶¶ 9-11, 14-17. Contrary to California's misleading assertions, Mr. Brase offers no opinion as to the nature of the margins. Indeed, the same type of simple calculations are performed in the Declaration of Susan Graydon filed by California (Dkt. No. 6785). Ms. Graydon is an employee of the California Attorney General's Office and is not an expert witness.

[3] "Palermo Decl., Ex. __" refers to the Declaration of Christopher C. Palermo in Support of Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s Opposition to Plaintiffs' Motion for Partial Summary Judgment, and the exhibits annexed thereto, Dkt. No. 6798.

approximately $6.8 million in reimbursement payments for Mylan's furosemide. *See id*. In contrast, none of the drugs that California contends Mylan ignored appear on this list.

Moreover, California ignores the fact that the examples cited by Mylan in its opening brief are consistent with the margins California paid for all of the Mylan Subject Drugs. Mylan's expert, Prof. Bradford, calculated the average margin California paid for all of the Mylan Subject Drugs to what Prof. Bradford describes as marginal pharmacies[4] during the relevant time period at just $3.67. *See* Palermo Decl. Ex. W, at 91-92. Moreover, Prof. Bradford calculated the average margin California paid for all drugs to marginal pharmacies during the relevant time period as $3.64. *See* Palermo Decl. Ex. W, at 79-80. Thus, not only are the examples of margins that Mylan cited in its opening brief consistent with the margins on all of the Mylan Subject Drugs, they are also consistent with the average margins California paid for all drugs during the relevant time period.

III. OTHER GROUNDS

California contends that its claims for lorazepam and clorazepate are not barred by the *res judicata* effect of the final judgment entered in the Lorazepam/Clorazepate Action or the release contained in the settlement agreement entered in that action between California and Mylan because the Lorazepam/Clorazepate Action concerned antitrust claims, and its claims against Mylan in this action arise under the CFCA. This argument is meritless.

The doctrine of *res judicata* bars claims that arose from "the same *transactional* nucleus of facts," as a previously litigated action between two parties that could have been

[4] These marginal pharmacies are the pharmacies with the highest costs of dispensing drugs. *See* Palermo Decl. Ex. W, at 56-57. They tend to be independent pharmacies located in geographically isolated parts of the state that also tend to have a high proportion of Medicaid beneficiaries *per capita*. *See id.* Participation by these pharmacies in the Medi-Cal program is therefore critical to ensure that California does not run afoul of its obligation to provide adequate access to quality care, as required by the Ninth Circuit in *Orthopaedic Hospital*.

brought in the previous litigation. *Tahoe-Sierra Preservation Council v. Tahoe Regional Planning Agency*, 322 F.3d 1064, 1078 (9th Cir. 2003). The release in the Lorazepam/Chlorazepate Action similarly releases all claims that "could have been asserted in that action" that arose out of the "facts, matters, *transactions*, events, occurrences, acts, disclosures, statements, omissions, or failures to act" alleged in the Lorazepam/Clorazepate Action. (Palermo Decl., Ex. D, at Sections I(U), I(Y), and IV(D) (emphasis added).)

There is no dispute that the claims at issue in the Lorazepam/Clorazepate Action arose from transactions that are also at issue in this action, namely Medi-Cal reimbursement payments for Mylan's lorazepam and clorazepate. Nor is there any dispute that the alleged harm to California is the same in both actions, namely that California was caused to pay inflated reimbursement payments for lorazepam and clorazepate. That California's claims against Mylan in the Lorazepam/Clorazepate Action purportedly arose from antitrust law as opposed to the CFCA is no help to California. As discussed *supra* at Point I, California was on inquiry notice of the facts it alleges gives rise to its claims against Mylan, in July 1998, five months prior to the commencement of Lorazepam/Clorazepate Action in December 1998, and more than two and a half years before the execution of the settlement agreement. California could have brought CFCA claims for reimbursement payments for Mylan's lorazepam and clorazepate in the Lorazepam/Clorazepate Action, and the principle of *res judicata* precludes it from seeking to recover those claims here. *Contra*, *Mass. v. Mylan Labs.*, No. 03-11865-PBS, 2009 U.S. Dist. LEXIS 20332, (D. Mass. March 11, 2009).

California contends that issues of fact exist as to its claims against Mylan Inc. because, in certain of its SEC filings, Mylan Inc. has stated that it is engaged in the manufacturing, marketing and distribution of generic drugs through its subsidiary Mylan

Pharmaceuticals Inc. This evidence does not create a question of fact as to Mylan Inc.'s liability. Statements about corporate subsidiaries in SEC filings are not sufficient to overcome the presumption of corporate separateness. For example, in *Freudensprung v. Offshore Technical Services, Inc.* 379 F.3d 327, 346-47 (5th Cir. 2004), the Fifth Circuit Court of Appeals stated that:

> Although Freudensprung insists that WWAI is indistinguishable from Willbros Group, he only offers as evidence various printouts from websites – primarily SEC filings related to all the Willbros entities, which are collectively referred to in these documents as "The Company." While such documents might arguably establish the existence of some corporate relationship between WWAI and the other Willbros entities, they are insufficient to overcome the presumption of corporate separateness.

Id.; *contra, Mass. v. Mylan Labs.*, 2009 U.S. Dist. LEXIS 20332.

CONCLUSION

For the foregoing reasons, and the reasons set forth in Mylan's Memorandum of Law in Support of its Motion for Partial Summary Judgment, Mylan respectfully requests that the Court grant its motion for partial summary judgment and dismiss all claims against Mylan that arose before July 1999, all claims arising from reimbursement payments for clorazepate and lorazepam, and all claims against Mylan Inc., and grant Mylan such other, further, and different relief as the Court deems to be just and proper.

Dated: January 15, 2010

Respectfully Submitted,

/s/ Christopher C. Palermo

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on January 15, 2010, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Christopher C. Palermo
Christopher C. Palermo